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ORIGINAL ARTICLE

Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study

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Abstract
Introduction Surgical decompression for lumbar spinal stenosis (LSS) has been associated with poorer outcomes in patients with pronounced low back pain (LBP) as compared to patients with predominant leg pain. This cross registry study assessed potential benefits of the interlaminar coflex® device as an add-on to bony decompression alone.
Methods Patients with lumbar decompression plus coflex® (SWISSspine registry) were compared with decompressed controls (Spine Tango registry). Inclusion criteria were LSS and a preoperative back pain level of ≥5 points. 1:1 propensity score-based matching was performed. Outcome measures were back and leg pain relief, COMI score improvement, patient satisfaction, complication, and revision rates.
Results 50 matched pairs without residual significant differences but age were created. At the 7–9 months follow-up interval the coflex® group had higher back ($p = 0.014$) and leg pain relief ($p < 0.001$) and COMI score improvement ($p = 0.029$) than the decompression group. Patient satisfaction was 90 % in both groups. No revision was documented in the coflex® and one in the decompression group (2.0 %).
Discussion In the short-term, lumbar decompression with coflex® compared with decompression alone in patients with LSS and pronounced LBP at baseline is a safe and effective treatment option that appears beneficial regarding clinical and functional outcomes. However, residual confounding of non-measured covariables may have partially influenced our findings. Also, despite careful inclusion and exclusion of cases the cross registry approach introduces a potential for selection bias that we could not totally control for and that makes additional studies necessary.

Keywords Lumbar spinal stenosis · Back pain · Decompression · Dynamic stabilization · Interlaminar spacer

Introduction

Lumbar spinal stenosis (LSS) is a degenerative and disabling disease, especially in the elderly over age 65 [1]. Compression of neural structures may cause claudication with dermatomal leg pain and reduced walking capacity. LSS can, however, also present with a stronger low back pain (LBP) component. Back pain in LSS may be caused by facet joint or disc degeneration, or by segmental instability.

Different therapeutic approaches exist for treating LSS. The first treatment option is conservative therapy [2]. If patient symptoms worsen and/or conservative treatment fails, surgical decompression becomes a treatment option with potentially favorable results [3, 4]. In a 10-year perspective, decompression appears to be beneficial over conservative treatment [5].

Several surgical decompression techniques have been described, however, the decompression itself can have

On behalf of the SWISSspine and Spine Tango Registry groups.

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some limitations in LSS patients, as it may result in an instability of the spinal segment requiring additional or later stabilization [6]. Furthermore, preoperative predominant LBP is associated with poorer outcomes after sole decompression in LSS patients [7, 8]. In these patients LBP seems to be insufficiently addressed by decompression alone [8] and an additional stabilization might be beneficial. However, rigid stabilization may not always be necessary and a dynamic implant preserving some segmental motion might be sufficient.

Interspinous-based stabilization after surgical decompression has been suggested as an option for these patients. One of these implants is the dynamic coflex® device (Paradigm Spine, LCC, New York, NY), originally presented as "Interspinous U" in France [9]. It is a compressible U-shaped titanium device that is interposed between the laminae and spinous processes after bony decompression in contrast to most other spacers which are implanted between the spinous processes only. Coflex was invented as an alternative to definitive fusion in the sense of a dynamic stabilization of a lumbar motion segment in combination with decompressive surgery.

This concept was supported by biomechanical studies of cadaver specimens demonstrating an increasing stability and a decreasing intradiscal pressure during extension after coflex® implantation, whereas this effect was only small in axial rotation, lateral bending, and flexion [10]. Another biomechanical investigation demonstrated that after partial segmental destabilization the coflex® device offered non-rigid fixation and re-stabilization in flexion, extension, and in axial rotation [11].

The aim of the current study was to compare clinical outcomes of coflex® with bony decompression versus decompression alone based on real-life data from two large spine registries.

Materials and methods

Registries

SWISSspine is a nationwide governmentally mandated registry following the principle of coverage with evidence development. The setup of the registry was already reported [12]. Surgeon-based data on intervention and follow-up, as well as patient-based preoperative comorbidity and pre- and postoperative Core Outcome Measures Index (COMI) forms are documented for all implanted interspinous/interlaminar spacers in Switzerland since February 2009.

Spine Tango is a voluntary registry under the auspices of Eurospine, the Spine Society of Europe [13]. It captures physician-based primary and follow-up data on surgical and conservative spinal treatments and uses the COMI as the official patient-based outcome instrument. Both registries are hosted at the Institute for Evaluative Research in Medicine at the University of Bern in Switzerland.

According to the SWISSspine guidelines, patients with general infection signs, medication, alcohol or drug abuse, psychosocial flags, adipositas, or spondylolisthesis are strictly excluded from an interspinous spacer implantation. Within the registry, coflex® was classified as an interlaminar device for treating patients with dynamic spinal stenosis or facet hyperpression syndrome.

The control group with decompression alone was derived from the Spine Tango registry based on the following in- and exclusion criteria: involved segments between L1/2 and L5/S1, lumbar spinal stenosis with or without disc degeneration, no other documented degenerative diseases (such as black disc, disc herniation, adjacent segment degeneration, facet joint arthrosis, degenerative spondylolisthesis, spondylosis, spondylarthrosis, or degenerative deformity), mono- or bisegmental decompressive surgery, no non-degenerative spondylolisthesis, no previous spine surgery, duration of the preoperative conservative treatment $\leq$12 months, ASA status 1 or 2, no additional spinal pathologies, no fusion, no rigid stabilization, no dynamic stabilization, no percutaneous measures, or no anterior access. To address patients with pronounced back pain, patients with a preoperative back pain below 5 NRS points (0–10) were excluded, similar to the approach used in the related FDA IDE trial [14].

Outcome measures

Outcome measures were back, leg, and maximum pain (the worse of the two pain locations) on numerical rating scales, COMI score, patient satisfaction, patient perception of treatment effectiveness, quality of life, complications, and revisions. The COMI is a short, self-administered outcome instrument consisting of seven questions to evaluate the following five dimensions: pain, back-related function, symptom-specific wellbeing, general quality of life, and disability (social and work) [15]. Additionally, the proportion of patients who achieved the minimum clinically relevant change (MCRC) of 2 points in pain and in the COMI score were assessed [16].

Statistical analyses

We performed a matched analysis of patients receiving coflex® with decompression versus patients with decompression alone. The propensity score method was used to adjust for potential confounding, as described in detail by Rosenbaum and Rubin [17]. In brief, an individual's propensity score is defined as their conditional probability of being exposed to coflex® with decompression versus decompression alone, given the observed covariates. Two

patients with the same propensity score have an equal estimated probability of exposure to the one or the other treatment. If one was exposed to coflex® with decompression and the other to decompression alone, the exposure allocation could be considered random, conditional on the observed covariates.

The individual propensity scores were obtained from a multiple logistic regression model with the following covariates: patient age (continuous) and sex (male, female), number of treated levels (1, 2), involvement of L1/2 (yes, no), L2/3 (yes, no), L3/4 (yes, no), L4/5 (yes, no), L5/S1 (yes, no), discectomy (yes, no), flavectomy (yes, no), laminotomy (yes, no), hemilaminectomy (yes, no), laminectomy (yes, no), facet joint resection (yes, no), preoperative back (continuous) and leg pain (continuous), and COMI score (continuous), as well as length of COMI follow-up in days (continuous). The propensity scores were then fed into a greedy matching algorithm for 1:1 matching, using the "OneToManyMTCH" SAS Macro presented by Parsons [18]. For the comparison of matched pairs the Chi square test for categorical and the paired *t* test for continuous covariates were used.

The significance level was set to 0.05 throughout the study. All statistical analyses were conducted using SAS 9.4 (SAS Institute, Inc., Cary, NC, USA).

Results

56 patients with decompression and coflex® and 299 patients with decompression alone were identified based on the in- and exclusion criteria. 1:1 matching resulted in 50 patient pairs with a mean follow-up interval of 9.2 months for the coflex® and of 6.9 months for the decompression group. Patients and treatment characteristics are summarized in Table 1. No residual significant differences but age remained in the matched pairs.

Table 2 shows the results of the group comparison for the outcome parameters. The coflex® group showed significantly lower postoperative back ($p = 0.022$) and leg pain ($p < 0.001$), and COMI score ($p = 0.022$), as well as significantly higher back ($p = 0.014$) and leg pain relief ($p < 0.001$) and COMI score improvement ($p = 0.029$) than the decompression group (Fig. 1). Also postoperative maximum pain and its relief (both $p = 0.002$) were significantly different between the groups in favor of the coflex® patients (Fig. 1).

Coflex® patients achieved the MCRC in back pain 18 % more frequently, MCRC in leg pain 26 % more frequently, MCRC in maximum pain 32 % more frequently, and MCRC in COMI score 12 % more frequently (Table 2). The latter difference was, however, not significant.

Patient satisfaction with care was similar in both groups with 90 % each. Patient perception of the effectiveness of the treatment was slightly, but not significantly better in the coflex® group (Table 2). Also, quality of life was slightly, but not significantly better in the coflex® group (Table 2).

No complications and no revision were observed in the coflex® group during the mean follow-up time of 9.2 months. In the control group a dural lesion in one patient and a bleeding in the spinal canal with consequent secondary hematoma evacuation during hospitalization in another patient were documented.

Discussion

The current study showed superior pain alleviation and functional improvement in patients with LSS and pronounced back pain who were treated with decompression and dynamic stabilization with a coflex® interlaminar device compared to decompression alone.

Several studies have demonstrated the effectiveness of coflex® describing a significant improvement of functional parameters, including back and leg pain and Oswestry score, after decompression with additional coflex® stabilization in LSS patients [14, 19–23].

There are two publications comparing coflex® after bony decompression with decompression alone in patients with LSS [22, 24]. Kumar's findings are in line with those of the current study where the improvement of ODI score, NRS scores for leg and back pain as well as the improvement of the SF-36 score was significantly greater in the coflex® group than in the control group, and no significant differences in complication rates between the groups were seen [24]. In contrast Richter et al. could not find differences in outcome and the authors concluded that the evidence of efficacy of the device and its right indications must still be considered as unknown [22]. But the 31 patients in each group were not randomized or matched and the authors themselves speculated that their results might possibly be an effect of patient selection [22].

A double-blinded RCT could not show any differences in clinical outcomes between patients receiving standard decompressive surgery and those receiving coflex® but without bony decompression. This non-recommended use of coflex® may explain the fairly high reoperation rate of 29 % compared to 8 % in the conventional group [25].

On the other hand studies comparing coflex® with decompression versus interbody fusion in patients with LSS showed similarly good clinical outcomes [19, 23]. The FDA IDE trial demonstrated equivalent or superior clinical outcomes at 24 months follow-up in ZCQ and the SF-12 physical component after coflex® as compared to fusion. Furthermore, advantages over instrumented fusion were also shown for perioperative outcomes such as length of stay, blood loss, and operation time [14]. A cost-

Table 1 Patient characteristics in the treatment groups

Characteristics	Matching 1:1		
	Coflex® with decompression ($n = 50$)	Decompression alone ($n = 50$)	Comparison (p value)
Mean age in years (SD)	67.7 (11.0)	63.0 (14.6)	0.05
Age range	46.5–89.6	25.5–86.9	–
% Female	50.0	48.0	0.84
Bisegmental (%)	20.0	16.0	0.60
Segment L1/2 (%)	–	–	–
Segment L2/3 (%)	2.0	4.0	0.56
Segment L3/4 (%)	26.0	24.0	0.82
Segment L4/5 (%)	60.0	58.0	0.84
Segment L5/S1 (%)	8.0	14.0	0.34
Discectomy (%)	14.0	6.0	0.18
Flavectomy (%)	68.0	62.0	0.53
Laminotomy (%)	62.0	62.0	1.0
Hemilaminectomy (%)	10.0	12.0	0.75
Laminectomy (%)	2.0	2.0	1.0
Facet joint resection (%)	70.0	66.0	0.67
Back pain at baseline (SD)	7.1 (1.5)	7.0 (1.6)	0.64
Leg pain at baseline (SD)	7.0 (2.2)	7.4 (2.2)	0.34
Maximum pain at baseline (SD)	8.0 (1.4)	8.0 (1.5)	0.80
COMI score at baseline (SD)	7.8 (1.6)	7.9 (1.3)	0.62
Follow-up interval in months (SD)	9.2 (7.6)	6.9 (6.5)	0.10

SD standard deviation

effectiveness analysis of the respective FDA IDE trial data showed lower 5-year costs for patients treated with coflex® compared to those treated with fusion [26]. The differences were even higher for two-level treatments.

Different indications for the use of coflex® within different settings were published but there is still no high evidence about a beneficial effect of the coflex® device with decompression compared to decompression alone. Especially in patients with pronounced preoperative LBP additional stabilization might have a benefit, but the indication of coflex® to fill this gap could not be verified so far. The aim of the current analysis was to evaluate this possible benefit of coflex® in combination with decompression compared to decompression alone in patients with LSS and LBP. Therefore, the results of the current study might be related to the selected patient sample by only including cases with a LBP intensity of at least 5 points. Our findings may help to better define the indication of decompression with additional dynamic stabilization with an interlaminar device as compared to decompression alone. Based on data from the SPORT trial Tosteson et al. estimated the adjusted mean QALY for decompression in patients with LSS to be 2.95 [27], whereby these patients did not have to have a predominant low back pain component. Using data from the FDA IDE RCT of coflex® versus fusion, Schmier et al. calculated 5-year patient reported utilities in LSS patients with predominant low back pain to be 2.97 QALYs for fusion and 3.02 for coflex® cases [26]. In these patients, decompression alone may result in lower QALYs as in the SPORT trial because decompression of the stenosis is typically successful in relieving symptoms of neural compression, but it often does little to address the mechanical back pain and progressive degenerative disc disease which is often associated with the stenotic disease state. Facet degeneration, in particular, can lead to persistent or worsened back pain, and the foraminal height is at risk of decreasing over time. Hence, the therapeutic sustainability of decompression may wane over time [24].

An explanation for the seemingly better results of coflex® as compared with other interspinous spacers may lie in its concept including direct bony decompression with interlaminar positioning as opposed to the indirect decompression by interspinous positioning in most other systems. Within the meta-analysis of Wu et al. the pooled VAS back and leg pain relief comparing interspinous spacers versus decompression alone did not find any significant differences [28]. In three of these investigations, however, the devices were inserted without decompression: X-Stop® (Medtronic Inc., Minneapolis, MN) [29], Aperius® (Medtronic, Switzerland) [30], and coflex® without decompression [25].

Table 2 Outcome measures in the treatment groups

Outcome measures	coflex® with decompression ($n = 50$)	Decompression alone ($n = 50$)	Comparison (p value)
NRS back pain relief[a]	3.8 (2.6)	2.5 (3.1)	0.014
NRS leg pain relief NRS[a]	4.3 (2.9)	2.5 (3.0)	<0.001
NRS maximum pain relief NRS[a]	4.1 (2.9)	2.3 (3.0)	0.002
NRS COMI score improvement[a]	3.7 (3.2)	2.5 (2.5)	0.029
MCRC of 2 points in back pain (%)	78.0	60.0	0.052
MCRC of 2 points in leg pain (%)	80.0	54.0	0.006
MCRC of 2 points in max pain (%)	76.0	44.0	0.001
MCRC of 2 points in COMI score (%)	66.0	54.0	0.22
Satisfaction: satisfied (%)	90.0	90.0	0.44
Satisfaction: neither/nor (%)	8.0	4.0	
Satisfaction: dissatisfied (%)	2.0	6.0	
Assessment: helped (%)	80.0	66.0	0.29
Assessment: neither/nor (%)	14.0	24.0	
Assessment: not helped (%)	6.0	10.0	
Quality of life: good (%)	36.0	26.0	0.50
Quality of life: moderate (%)	40.0	42.0	
Quality of life: bad (%)	24.0	32.0	
Dural lesion, *n* (%)	–	1 (2.0)	1.0
Vascular injury, *n* (%)	–	1 (2.0)	1.0
Revision, *n* (%)	–	1 (2.0)	1.0

MCRC minimum clinically relevant change

[a] Mean (standard deviation)

Only the DIAM® (Sofamor Danek, France) was inserted as adjunct to decompression [31].

In our coflex® group no complication and revisions were observed, but the follow-up time was rather short with a mean of 9.2 months. Zang et al. [32] reported a complication rate of 9.8 % after a mean follow-up time of 27.6 months, Xu et al. [33] reported 8.4 % after a mean follow-up of 30.3 months. The investigations of Richter et al. [22] and Kumar et al. [24] did not find significantly different complication and revision rates of coflex® as adjunct to decompression compared to decompression alone. In the Moojen investigation, the complication and reoperation rate was reported to be higher for additional coflex® implantation compared to decompression alone and the possible reason was mentioned before [25, 28]. The low complication rate might lead to the assumption of a general underreporting of complications and reoperations within the unmonitored registries. This would, however, mean that the relative comparison of these rates is still valid, but not their absolute rates. For the Spine Tango registry this assumption could already be disproved by showing even higher rates for dural lesion in an investigation of Spine Tango data compared to a study from the Swespine registry [6]. Hence we assume a valid documentation.

Further limitations are the restricted comparability of indication of use and outcome parameters for this cross registry analysis. Within the SWISSspine and Spine Tango registries the indication was lumbar spinal stenosis. To reach an even higher comparability additional matching parameters applied were the different decompression types such as discectomy, flavectomy, laminotomy, hemilaminectomy, laminectomy, and facet joint resection. But due to different documentation forms of the two registries, parameters used for the propensity score and comparable outcome parameters were limited. This aspect could have potentially led to residual confounding of non-measured covariables and may have partially influenced our findings. Also, despite careful inclusion and exclusion of cases the cross registry approach introduces a potential for selection bias that we could not totally control for.

With a mean follow-up time of 6.9 and 9.2 months no long-term data were available. The question whether the benefit of an additional coflex® implantation will remain after longer periods can hence not be answered with our results. The investigation of Richter et al. did not find any deterioration of symptoms or decline of benefit within the 2-year follow-up for the coflex® and the decompression group [22]. Also, Kumar et al. reported stable results over a 2-year follow-up period with a VAS back pain

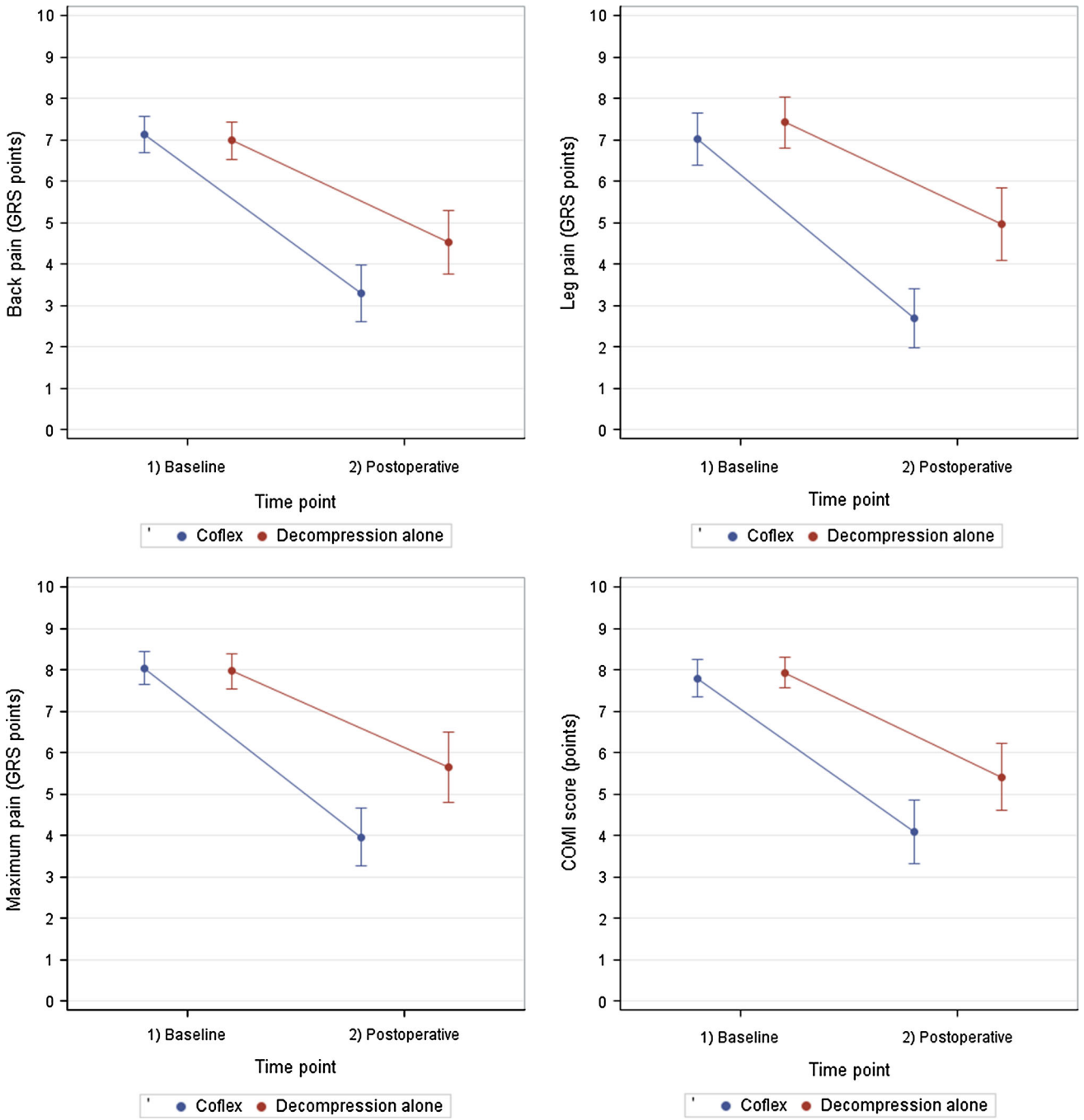

Fig. 1 Pre- and postoperative back, leg, and maximum pain, as well as COMI score in the treatment groups with 95 % confidence intervals

improvement from preoperative 54.4 to 32.9, 32.2, and 29.5 at 6 months, 1 and 2 years postoperative, and a VAS leg pain improvement from preoperative 63.5 to 19.8, 12.5, and 7.8, respectively [24]. On the other hand radiographic analyses showed a decrease of the postoperatively increased foraminal height over time [21, 24], but this finding was not associated with changes in clinical outcome [21]. Finally, Hyun et al. have meanwhile presented level 1 evidence from the above-mentioned FDA IDE trial about the four-year outcomes of patients treated with coflex® for LSS with predominant low back pain. Compared to posterolateral fusion, coflex® interlaminar stabilization was associated with improved clinical, safety, and radiographic results, especially maintenance of index level motion and, opposed to the aforementioned studies, foraminal height. Foraminal height maintenance and the absence of increased motion at the adjacent levels were hypothesized as factors associated with longer-term

therapeutic sustainability and durability. These observations may allow the assumption that the clinical outcomes we observed at a relative short-term follow-up will remain stable over time.

Conclusion

We conclude that additional interlaminar implantation of coflex® with bony decompression is a safe and effective way to treat patients with lumbar spinal stenosis and seems to generate superior short-term outcomes in patients with pronounced LBP compared to decompression alone. However, additional longer-term studies are required to determine the potential advantage of coflex® combined with decompression vs. decompression alone for patients with LSS with significant LBP (NRS >5).

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